

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1020051	(X3) Date Survey Completed 04/02/2026
Name of Provider or Supplier Rm Lab Llc Dbc Express Lab	Street Address, City, State 7988 W Marigold St Ste 100, Boise, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A validation survey was conducted on April 2, 2026, with the following standard level deficiencies cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review laboratory's client service manual, patient test reports, and interview with the Technical consultant #1, the laboratory failed to follow the manufacturer's instructions (Siemens) and their own policy for specimen collection and handling with Activated Partial Thromboplastin Time (aPTT) for the 4 hour time frame prior to analysis 3 of 13 aPTT reviewed from July 1, 2025 to September 30, 2025 as evidenced by: 1. In review of the laboratory's client service manual, "separate plasma, use a plastic transfer pipette; remove the plasma to a plastic tube without disturbing the buffy coat. If testing is not completed within 4 hours, the plasma may be stored frozen at -20 C or below for up to 2 weeks or -70 C or below for long-term storage Room Temperature: 4 hours." 2.In review of the patient test reports for aPTT from July 1, 2025, to September 30, 2025, the following patients were over the 4-hour time frame: a.patient 3910530 collected 7/31/2025 at 1350 received in the laboratory 7/31 /2025 at 1756, 4 hours 6 minutes. b.Patient 392436 collected 8/14/2025 at 1134 received in the laboratory at 1817, 6 hours 43 minutes. c.Patient 3944681 collected 09</p>

/14/2025 at 1010 received in the laboratory at 1608, 5 hours 58 minutes. 3.In interview with Technical Consultant #1 at 1040 confirmed that the three patients' aPTT didn't come within the time frames listed in the client service manual.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Prothrombin times (PT) Based on review of the laboratory's policy, of the laboratory's mean of the normal patient range (MNPT) study, and interview with the General supervisor #1, the laboratory failed to have documentation to show volunteers were not on blood thinner or aspirin therapy while performing the MNPT on 12/16/2025 as evidenced by: 1.In review of the laboratory's policy for MNPT it states, "Prepare 20 sodium heparin (light blue top) tubes labeled with M1-M10 for males and F1-F10 for females. Take them to the phlebotomist that you are working with and explain to them that you need 20 normal patient samples from volunteers who are not on blood thinners or aspirin therapy ..." 2. In review of the laboratory's MNPT study, the laboratory could not identify who the individuals were, nor could they provide documentation that the individuals were not on blood thinner or aspirin therapy. Male 7 had a PT of 13. 6/ INR = 1.23 Male 10 had a PT = 14.4/ INR 1.3. 3.In interview with the general supervisor #1 at 1100, he stated that he didn't know who the individuals were and did not have documentation to see if they were not on blood thinners or aspirin therapy. 4.The laboratory performed 56 PTs in 2025.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, manufacturer's instructions, and interview with General supervisor #1, the laboratory failed to monitor room temperature where supplies were stored in two of two rooms observed (phlebotomy room and draw storage) for the last two years as evidenced by: 1.The manufacturer's instructions for the Becton Dickison (BD) tubes (EDTA, Sodium Citrate, Sodium Floride, Serum Separator Tubes (SST) Tiger top state, "store at 4-25 degrees C." 2.The manufacturer's instructions for the BD protec swabs state, "store at 5-25 degrees C." 3.During a tour of the facility at 0858 the following supplies were stored in the phlebotomy room without temperature monitoring: a.20-BD SST lot#6007511 expiration date: 12-31-2026 b.22- BD EDTA

lot#5260186 expiration date 1-31-2027 c.56- BD SST tiger top lot# 5324136 expiration date 1-31-2027 4. During a tour of the facility at 0900 the following supplies were stored in the drawing storage: a. 100-Vaginal BD protec swabs lot#241257 expiration date: 9-30-2026. b. 49- BD K2EDTA lot#5260186 expiration date: 01-31-2027 c. 43- BD Sodium Fluoride lot#5101435 expiration date: 8-31-02026. d. The laboratory could not provide a temperature chart documentation for the room temperature in the phlebotomy or drawing storage rooms. 5. In an interview with the general supervisor at 0900, it was confirmed that the laboratory was not monitoring room temperature per the manufacturer's instructions.